

We claim:

1. A composition comprising a pharmaceutically acceptable carrier and an active agent complexed with glycyrrhizin wherein the active agent contains at least one nitrogen-containing moiety; and wherein the composition is substantially free of uncomplexed active agent.

2. The composition according to claim 1, wherein the glycyrrhizin is a glycyrrhizin acid and its biologically acceptable salts.

3. The composition according to claim 2, wherein the glycyrrhizinic is an 18-alpha glycyrrhizinic acid or 18-beta-glycyrrhizinic acid.

4. The composition according to claim 2, wherein the glycyrrhizinic acid is ionically complexed with the active agent.

5. The composition according to claim 2, wherein the active agent is famotidine.

6. The composition according to claim 2, wherein the active agent is buspirone.

7. The composition according to claim 2, wherein the active agent is sildenafil.

8. The composition according to claim 2, wherein the active is caffeine.

9. The composition according to claim 2, wherein the active agent is loratadine.

10. The composition according to claim 2, wherein the mole ratio of glycyrrhizinic acid to active agent is 1:1 to 1:3.

11. The composition according to claim 1, wherein the mole ratio of glycyrrhizin to active agent is 1:1 to 1:3.

12. The composition according to claim 1, wherein the nitrogen containing moiety is one or more of an acyclic or heterocyclic amine, amide, imine, imide and nitrile

13. The composition according to claim 1, wherein the active agent comprises abortifacients, ACE inhibitors, adrenocorticotrophic hormones, α -adrenergic agonists, α -adrenergic blockers, α -glucosidase inhibitors, anabolic steroids, narcotic analgesics, non-narcotic analgesics, anorexics, anthelmintics, antiallergics, antialopeicals, antiamebics, antianginals, antiarrhythmics, antiarthritics, antiasthmatics, antibiotics, anticholinergics, anticonvulsants, antidepressants, antidiabetics, antidiarrheals, antidotes, antidyskinetics, antiemetics, antiestrogens, antifungals, antiglaucoma agents, antigout agents, antihistaminics, antihypertensives, nonsteroidal antiinflammatories, antimalarials, antimigraines, antineoplastics, antiparkinsonians, antipheochromocytoma agents, antipneumocystis, antiprostatic hyperplasia agent, antiprotozoals, antipruritics, antipsoriatics, antipsychotics, antipyretics, antirickettsials, antispasmodics, antithrombocythemics, antithrombotics, antitussives, antiulceratives, antivirals, anxiolytics, aromatase inhibitors, benzodiazepine antagonists, β -adrenergic antagonists, β -adrenergic blockers, bradycardic agents, bronchodilators, calcium channel blockers, carbonic anhydrase inhibitors, cardiotonics, choleretics, cholinergics, cholinesterase inhibitors, cholinesterase reactivators, CNS stimulants, cytoprotectants, decongestants, diuretics, dopamine receptor agonists, dopamine receptor antagonists, ectoparasiticides, emetics, expectorants, fibrinogen receptor antagonists, gastric secretion inhibitors, gastroprokinetics, hemostatics, histamine H₂ receptor antagonists, immunomodulators, immunosuppressants, keratolytics, MAO inhibitors, mucolytics, muscle relaxants, mydriatics, narcotic antagonists, nootropics, oxytocics, potassium channel activators, respiratory stimulants, sedatives, hypnotics, serenics, serotonin receptor agonists, serotonin receptor antagonists, serotonin uptake inhibitors, thrombolytics, tocolytics, vasodilators, and vasoprotectants.

14. A pharmaceutical dosage form comprising the composition of claim 1.

15. The dosage form of claim 14, wherein the dosage form is selected from the group consisting of a reconstituted powder, a soluble, and edible film sachet, a liquid for oral or parenteral administration, an effervescent tablet, a chewable tablet, a mucosal surface-

coating hydrocolloid film, a fast dissolving intraoral wafer, a troche, a lozenge, a nasal spray, a powder for inhalation, a mucoadhesive device for buccal, rectal or vaginal administration, a controlled release tablet and a capsule containing enteric microcapsules.

16. The dosage form of claim 14, wherein the dosage form further comprises at least one reagent selected from the group consisting of a water soluble polymer, a water insoluble polymer, an emulsifier, a plasticizer, a taste modifier, a coloring agent, a preservative, a permeation enhancer, a stabilizer, an inert filler, a binder, a thickening agent, a buffering agent, a lipid vehicle, a metabolism inhibitor and a glidant.

17. A method for making the composition of claim 1, comprising mixing an active agent and glycyrrhizin in an aqueous solvent.

18. The method of claim 17, wherein the active agent is mixed with a dispersion of glycyrrhizin in an aqueous solvent.

19. The method of claim 17 when the aqueous solvent is water.

20. The method of claim 17, comprising the additional step of recovering the resulting complex.

21. The method of claim 20, wherein the complex is recovered using spray drying.

22. The method of claim 20, wherein the complex is recovered using freeze drying.

23. The method of claim 17 wherein the aqueous solvent is a hydroalcoholic solvent.

24. The method of claim 23 wherein the active agent is mixed with glycyrrhizin which is dispersed or dissolved in the hydroalcoholic solvent.

25. The method of claim 23, comprising the additional step of recovering the resulting complex.
26. The method of claim 25, wherein the complex is recovered by spray drying.
27. The method of claim 25, wherein the complex is recovered by freeze drying.
28. The method of claim 23, wherein the hydroalcoholic solvent is a mixture comprising water and one or more of methanol, ethanol or isopropanol.
29. The method of claim 28, wherein the weight percentage of alcohol in the hydroalcoholic solvent is greater than 10% and less than 90%.
30. The method of claim 28, wherein in the weight percentage of alcohol in the hydroalcoholic solvent is greater than 20% and less than 80%.
31. A method of making the complex of claim 1, comprising mixing a mixture of glycyrrhizin and an active agent with an aqueous solvent;
32. The method of claim 31, wherein the aqueous solvent is water.
33. The method of claim 31, wherein the aqueous solvent is a hydroalcoholic solvent.
34. The method of claim 31, wherein the hydroalcoholic solvent comprises water and one or more of methanol, ethanol or isopropanol.
35. The method of claim 34, wherein the weight percentage of alcohol in the hydroalcoholic solvent is greater than 10% and less than 90%.
36. The method of claim 34, wherein in the weight percentage of alcohol in the hydroalcoholic solvent is greater than 20% and less than 80%.

37. The method of claim 31, comprising the additional step of recovering the resulting complex.

38. The method of claim 37, wherein the complex is recovered using spray drying.

39. The method claim 38, wherein the complex is recovered using freeze drying.

40. A method for enhancing the water solubility of an active agent comprising forming a complex with glycyrrhizin wherein the active agent contains at least one nitrogen-containing moiety.

41. The method of claim 40, wherein the water solubility of the active agent in complexed form is at least five times greater than that of the active agent is non-complexed form.

42. The method of claim 41, wherein the water solubility of the active agent in complexed form is at least ten times greater than that of the active is non-complexed form.

43. The method of claim 42, wherein the water solubility of the active agent in complexed form is at least twenty times greater than that of the active is non-complexed form.

44. The method of claim 43, wherein the water solubility of the active agent in complexed form is at least fifty times greater than that of the active is non-complexed form.